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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/792,256

03/02/2004

Edward A. Schroeppel

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SINSHEIMER JUHNKE LEBENS & MCIVOR, LLP

1010 PEACH STREET

P.O. BOX 31

SAN LUIS OBISPO, CA 93406

EXAMINER

GETZOW, SCOTT M

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/792,256	<b>Applicant(s)</b> SCHROEPPEL ET AL.	
	<b>Examiner</b> Scott M. Getzow	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 19, 21, 22, 24, 25, 27-31, 34, 35, 37-41, 43-45, 64-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) remainder is/are rejected.
- 7) ☒ Claim(s) 44 and 45 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/10/08, 2/20/09</u> .  | 6) <input type="checkbox"/> Other: _____                          |

***Claim Rejections - 35 USC § 103***

1. Claims 1-10,19,21,22,24,25,27-31,34,35,37-41,68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herbst et al (6,021,347) in view of Hoffmann (6,009,345).

Figure 1 of Herbst shows a power source, and circuitry coupled to the power source, as well as at least one electrode 11,12 that can deliver dc current for at least one minute. Figure 2 shows a catheter which can deliver drugs, and can also be used as an electrode. Hoffman teaches the use of an electrode array, as shown in figure 1b, where the electrodes are 28,30,36,38. The electrodes are used to 'steer' therapeutic agents such that the agents go along a predetermined path to enter the desired site in the patient's body. To use such a electrode array would have been obvious in that such steering would be helpful to maximize the benefits of drug therapy by allowing the drugs to enter at the desired location, and also such would be a combination of known prior art elements combined to yield a predictable result. The subject matter of claims 2-9 are considered to be intended uses which are capable of being performed by the structure of Herbst and Hoffman. The skilled artisan would know that treatment times and voltage levels can be varied depending upon patient conditions, and the type of tumor being treated. To be able to vary treatment times and voltage levels is well within the skill of the ordinary artisan. Column 5 of Herbst teaches that the dc current can be pulsed, and the polarity of the signals can be switched. Re claim 10, the device is considered to have an electrical port, as shown in figure 1, in order to receive the therapeutic pulses. Re claims 19,21,22,24,25,27-31,35, as stated above, the skilled

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artisan would know patients differ as to the proper stimulation levels and duration, and the structure of Herbst and Hoffmann could accomplish such uses if desired. Re claim 34,37, where the device is located is not a structural limitation. Further, to enable the device to be implanted is obvious in that medical devices frequently are able to be implanted, and the ability to make the device implantable is well within the skill of the ordinary artisan. Re claim 27, the electrode array of Hoffmann could be 'arranged in an arc' if desired, depending upon user preferences and what the most effective location for the electrodes would be for the particular patient. Re claim 38, the device of Herbst is capable of reversing polarity of the output pulses. Re claim 39,40, to make the electrode internally or externally connected to the catheter is considered to be a design choice. As shown in figure 2 of Herbst, the electrode could be the catheter as well, and thus be considered to be internally and externally connected to the catheter. Re claim 41,68, figure 2 of Herbst shows a plurality of apertures.

2. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Herbst et al (6,021,347) in view of Hoffmann (6,009,345), and further in view of Kucharczyk et al (6,599,274).

Figure 8 of Kucharczyk shows a membrane which can be considered to be a porous drug absorbing material which can be in contact with a portion of an abnormal tissue growth, if desired. To use such with the device of Herbst and Hoffman would have been obvious in that such would be a combination of known prior art elements combined to yield a predictable result. Further, to alter the rate of drug therapy would provide

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beneficial effects to the patient by allowing a more accurate dosage of drugs to reach the patient, while preventing overdosing the patient.

3. Claims 64-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herbst et al (6,021,347) in view of Hoffmann (6,009,345), and further in view of Balbierz et al (2002/0026188) and Kucharczyk et al (6,599,274).

Figure 24 of Balbierz teaches a catheter electrode 18 having a porous extension, including apertures 23. As mentioned above, Kucharczyk teaches membrane which can regulate fluid flow across it. To use the extension, and the porous membrane would have been obvious since such would merely be a combination of know prior art elements combined to yield a predictable result, and the use of a extension would allow for greater treatment options, where the electrode catheter can cover a greater area of tissue to be treated. Re claim 66, as mentioned above, the structure of Herbst and Hoffmann are considered to encompass an electrical port contact. Also, claims 65,67 are intended uses capable of being performed by the device of Herbst.

4. Claims 1-10,19,21,22,24,25,27-31,34,35,37-41,68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herbst et al (6,012, 347).

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The structure of the Herbst device could be fairly interpreted in an alternative way, than that set forth above. For example, working electrode 11 can be considered the 'at least one electrode' of applicant's claim 1, and the counterelectrode 12 can be considered the 'electrode array'. Column 4 of Herbst states that 'more than one counterelectrode can be used in conjunction with one working electrode in order to distribute current flow throughout the tumor'. Thus, the counterelectrode can be positioned to form an array around the cancerous tissue in any manner desired. Further, column 5 of Herbst states that it is desirable to combine 'chemotherapy with an ECT procedure either concurrently or alternately', and also 'by combining chemotherapy with an ECT procedure, one is able to ensure fuller treatment of the tumor'. The electrode array 12 of Herbst would inherently 'steer' the therapeutic agent in a predetermined path when current is applied to the electrodes simultaneously with application of chemotherapy. The dependent claims are considered to be obvious over the teachings of Herbst since such are capable of being performed by the device of Herbst to provide effective treatment to the patient, as mentioned supra. Further, it would have been obvious to apply stimulation for at least one minute, if the conditions of the patient's tumor dictate that such treatment is appropriate.

5. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Herbst et al (6,021,347) in view of Kucharczyk et al (6,599,274).

See the rejection of claim 43 supra.

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6. Claims 64-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herbst et al (6,021,347) in view of Balbierz et al (2002/0026188) and Kucharczyk et al (6,599,274).

See the rejection of claims 64-67 supra.

### ***Double Patenting***

7. Claims 1-10,19,21,22,24,25,27-31,34,35,37-41,43,64-68 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,738,663 in view of Herbst et al (6,021,347), (and Kucharczyk et al (6,599,274) and Balbierz et al (2002/0026188). Re claim 1, as mentioned above, Herbst can be considered to teach an array of electrodes. To use such with the other structure of the claims of the parent patent would have been obvious since such would merely be the combination of known prior art elements combined to yield a predictable result. Further, to use the Kucharczyk and Balbierz references in combination with Herbst and the parent patent would have been obvious for reasons mentioned supra.

8. Claims 1-10,19,21,22,24,25,27-31,34,35,37-41,43,64-68 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,021,347 in view of Herbst et al (6,021,347), (and Kucharczyk et al (6,599,274) and Balbierz et al (2002/0026188). See rejection supra.

***Allowable Subject Matter***

9. Claims 44,45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott M. Getzow whose telephone number is (571) 272-4946. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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/Scott M. Getzow/  
Primary Examiner, Art Unit 3762